UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/869,198 | 01/24/2002 | Robert Douglas Gordon | JAB-1463 | 1206 |

7590 06/30/2004

Philip S Johnson
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003

| EXAMINER | |
|---|---|
| AKHAVAN, RAMIN | |
| **ART UNIT** | **PAPER NUMBER** |
| 1636 | |

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Applicant 06/23/04 RA

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/869,198 | GORDON ET AL. | |
| | Examiner | Art Unit | |
| | Ramin (Ray) Akhavan | 1636 | |

SM

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-22,24-52,54-57 and 59-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-22, 24-51, 53, 54-57, 59-72* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted. The groups are as follows:

1. Claim 1-4, 6-7, 11, 12, 15, 17, 18, 21, 39-49, 54-55, 65-67 and 72, drawn to nucleic acids encoding a VEGF-X protein, including CUB domain or a VEGF like domain, as well as a transgenic cell, tissue or organism containing the sequence depicted in Fig. 10, and a method of using said nucleic acids in a process for producing a VEGF-X protein and recovering the expressed protein from said host cell.
2. Claim 5, 13, 16 and 63-64, drawn to an antisense molecule hybridizing to a nucleic acid molecule encoding a VEGF-X protein and an expression vector comprising a nucleotide sequence encoding an antisense molecule and a host cell transformed with said vector.
3. Claim 8-10, 19, 20 and 31, drawn to a VEGF-X protein.
4. Claim 14, drawn to a pharmaceutical composition comprising nucleic acid molecules encoding VEGF-X.
5. Claim 22, 25-26 and 68-69, drawn to an antibody capable of binding a VEGF-X protein and a kit and method of identifying VEGF-X protein in a sample using an antibody.

6. Claim 24 and 70-71, drawn to a pharmaceutical composition comprising an antibody capable of binding a VEGF-X protein.
7. Claims 27-28, drawn to a method of identifying compounds, which modulate angiogenesis and products identified through such a method.
8. Claim 29, drawn to a pharmaceutical composition comprising a compound identified as a modulator of angiogenesis.
9. Claim 32, drawn to a method of inhibiting angiogenic activity in a subject using antisense molecules capable of hybridizing under high stringency to a nucleic acid encoding the VEGF-X protein from amino acid residue 23 to 345.
10. Claim 33, drawn to a method of inhibiting angiogenic activity in a subject using antibodies against a VEGF-X protein.
11. Claim 34, drawn to method of inhibiting angiogenic activity in a subject by implanting cells expressing an antibody against VEGF-X protein.
12. Claim 35, drawn to a method of treating or preventing any cancer, rheumatoid arthritis, psoriasis and diabetic retinopathy in a subject using an antisense molecule capable of hybridizing under high stringency to a nucleic acid encoding the VEGF-X protein from amino acid residue 23 to 345.
13. Claim 36, drawn to a method of treating or preventing any cancer, rheumatoid arthritis, psoriasis and diabetic retinopathy in a subject using an antibody against VEGF-X protein.
14. Claim 37, drawn to a method of promoting angiogenic activity in a subject by administering a therapeutically effective amount of a VEGF-X protein.

15. Claim 37, drawn to a method of promoting angiogenic activity in a subject by administering a therapeutically effective amount of an expression vector comprising a nucleic acid molecule encoding a VEGF-X protein.
16. Claim 37, drawn to a method of promoting angiogenic activity in a subject by administering a therapeutically effective amount of a pharmaceutical composition comprising a nucleic acid molecule encoding a VEGF-X protein.
17. Claim 38, drawn to a method of treating wounds from a varied group of maladies using a therapeutic amount of a VEGF-X protein.
18. Claim 50-51 and 60, drawn to a method of identifying compounds that inhibit or enhance angiogenic activity, where cells expressing a VEGF receptor and/or a neuropilin 1 or 2 receptor are contacted with said compound in the presence of VEGF-X protein and compounds so identified.
19. Claim 52 and 60-61, drawn to a method of inhibiting angiogenic activity or inappropriate vascularization comprising contacting a cell expressing a VEGF receptor and a neuropilin type receptor with a VEGF-X protein, CUB domain or VEGF like domain comprising sequences depicted in Fig. 10.
20. Claim 56, drawn to a pharmaceutical composition comprising a nucleic acid molecule encoding the protein with amino acid sequence comprising the amino acid sequence from position 40 to 150 of Fig. 10.
21. Claim 57 and 59, drawn to a method of treating disease condition associated with inappropriate angiogenesis comprising contacting the patient with a pharmaceutical

composition comprising a nucleic acid molecule encoding a polypeptide having the amino acid sequence from position 40 to 150 of Fig. 10.

22. Claim 62, drawn to a method of treating or preventing any cancer, rheumatoid arthritis, psoriasis and diabetic retinopathy, comprising administering to said subject an amount of a polypeptide having amino acid sequence from position 40 to 150 of Fig. 10.
23. Claim 62, drawn to a method of treating or preventing any cancer, rheumatoid arthritis, psoriasis and diabetic retinopathy, comprising administering to said subject an amount of a nucleic acid molecule having a CUB domain comprising the sequence from position 40 to 150 of Fig. 10.

The claims encompass 23 separate inventions. Restriction to one single invention is required under 35 U.S.C. 121 and 372. The inventions listed in Groups 1-47 do not relate to a single general inventive concept under PCT Rule 13.1, because under PCR Rule 13.2 which indicates that unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features (i.e. technical features that define a contribution which each of the inventions considered as a whole makes over the prior art). The separate inventions are structurally or mechanistically distinct enough that they do not share a single special technical feature.

It should be noted that certain groups contain the same claim(s) because the claim(s) as written are generic and link separate or distinct inventions, involving a different special technical feature. The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See MPEP § 1.475(e).

Group 1 is drawn to nucleic acids encoding VEGF-X. The special technical feature is the specific sequence (i.e. structure) with the prescribed functional correlation. No other group shares this special technical feature. Furthermore, this special technical feature would not be required to make VEGF-X, as such proteins could be made synthetically. This special technical feature is shared in claims drawn to vectors constructs comprising said nucleic acid molecules, as well as host cells or organisms transformed with said nucleic acid molecules.

The remaining groups each contain a distinct special technical feature that is not shared as amongst each other or Group I. The special technical features are as follows: in Group 2 (anitsense), Group 3 (VEGF-X protein), Group 4 (pharmaceutical composition comprising nucleic acid molecules encoding VEGF-X), Group 5 (antibodies), Group 6 (pharmaceutical compositions comprising an antibody), Group 7 (identifying angiogenesis modulators), Group 8 (pharmaceutical composition comprising compounds that modulate angiogenesis), Group 9 (inhibition of angiogenic activity using antisense), Group 10 (inhibition of angiogenic activity using antibodies), Group 11 (inhibition of angiogenic activity via cell implantation), Group 12 (treatment of cancer, etc. using antisense molecules), Group 13 (treatment of cancer, etc. using antibodies), Group 14 (promoting angiogenic activity by administering VEGF-X), Group 15 (method as in 14 but through administration of an expression vector), Group 16 (method as in 14 but with administration of nucleic acid molecules), Group 17 (treatment of wounds using VEGF-X protein), Group 18 (identification of compounds affecting angiogenic activity), Group 19 (inhibition of angiogenic activity), Group 20 (pharmaceutical composition comprising nucleic acid encoding 40-150 of Fig. 10), Group 21 (treating diseases associated with inappropriate

angiogenesis), Group 22 (treating or preventing cancer, etc. via protein administration) and Group 23 (treating or preventing cancer, etc. via nucleic acid administration).

For the reasons given above the inventions grouped 1-36 are distinct and each is drawn to a distinct special technical feature. Furthermore each group would require a separate search, thus restriction for examination purposes as indicated is proper. Applicant is advised that a reply to this restriction requirement must include an election for the invention (i.e. a single group) to be examined, for the reply to be complete, notwithstanding that the requirement be traversed (37 CFR 1.143). Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if none or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanies by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Conclusion***

Claims 1-72 encompass 23 separate inventions. Applicant is required to elect a single group, notwithstanding traversal.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramin (Ray) Akhavan whose telephone number is 571-272-0766. The examiner can normally be reached on Monday- Friday from 8:00-4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can

be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GERRY LEFFERS
PRIMARY EXAMINER